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To: NCIC OPPT/DC/USEPA/US@EPA, ChemRTK HPV/DC/USEPA/US@EPA, Rtk
Chem/DC/USEPA/US@EPA, Karen Boswell/DC/USEPA/US@EPA, tadams@therobertsgroup.net
cc:

Subject: Public comments

Attached please find the comments of the American animal protection community on the Flavor and Fragrance High Production Volume Consortium's test plan.

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- HPV test plan comments -- Ionone Deriv.pdf

July 29, 2002

Christine Todd Whitman, Administrator
U. S. Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Ave., N. W.
Washington, DC 20460

Subject: Comments on the Test Plan for Ionone Derivatives

Dear Administrator Whitman:

The following comments on the test plan for the Flavor and Fragrance High Production Volume Consortium's ionone derivatives category are submitted on behalf of People for the Ethical Treatment of Animals, the Physicians Committee for Responsible Medicine, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These animal protection and environmental organizations have a combined membership of more than ten million Americans.

The Flavor and Fragrance High Production Volume Consortium has developed a logically circumscribed category of structurally similar chemicals, including isomers and compounds differing only by a methyl group. This unequivocally meets the EPA criteria for establishing a chemical category under the HPV program. The Consortium has presented robust summaries that adequately address each health endpoint of the SIDS battery and has appropriately not called for any additional tests on animals. The ionone derivatives have already been tested on many animals, and any further testing would not enhance the understanding of their generally low toxicity. Moreover, these substances are used in both fragrances and food flavorings and are labeled Generally Recognized as Safe (GRAS) by the Food and Drug Administration. These substances have also been deemed safe for food use by the Joint Expert Committee on Food Additives for the World Health Organization.

Ionone derivatives are found mainly in plants containing beta-carotene. Human exposure is more likely to occur via consumption of natural fruits, vegetables, and nuts rather than products flavored with the ionone derivatives.

The Consortium's proposal is fully in keeping with items 1 and 8 of the October 1999 agreement, reiterated in the December 2000 *Federal Register* notice. Item no. 1 states that "participants shall conduct a thoughtful, qualitative analysis...Participants may conclude that there is sufficient data, given the totality of what is known about a chemical, that certain endpoints need not be tested." Participants sponsoring GRAS chemicals shall, according to item no. 8, "specifically consider whether the information available makes it unnecessary to



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proceed with further testing involving animals. As with all chemicals, before generating new information, participants should further consider whether any additional information obtained would be useful or relevant.”

We commend the Consortium’s comprehensive analysis of existing data and support the contention that no further tests on animals are warranted for this substance.

Thank you for the opportunity to comment. I can be reached at 757-622-7382, ext.1304, or via e-mail at *jessicas@peta.org*.

Sincerely,

Jessica Sandler, MHS
Federal Agency Liaison